UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

BOSTON DIVISION

KENNETH EUGENE BARRON, )
Plaintiff, )
v. )
UNITED STATES OF AMERICA )
Defendants )

CASE NO. 04-CV-40023 RCL

DECLARATION OF MICHAEL B. NELSON, D.O.

I, Michael B. Nelson, D.O., declare and state as follows:

1. I am currently the Chief of Health Programs for the Health Services Division, Bureau of Prisons (BOP) in Washington, D.C. I have been so employed since September 1999. In my capacity as Chief of Health Programs, I have had an ongoing active role in the development of the BOP policy and implementation guidelines regarding organ transplantation for inmates. I chair an advisory group appointed by the Medical Director, to review all requests for treatment which are characterized as "extraordinary care," to include many requests for organ transplants.

2. I have had no specific role in the evaluation of Mr. Barron for possible kidney transplant. To my knowledge I have not been consulted with regard to any

specific issues regarding Mr. Barron's medical condition.

3. BOP policy regarding organ transplantation was changed in February of 2000, in response to guidance from the Justice Department, as well as the increasing body of scientific literature supporting transplantation as a viable treatment option for certain conditions, such as renal failure. Contrary to the statements made in Mr. Barron's instant civil action, the revised BOP policy found in BOP Program Statement 6000.05, Chapter VI, §21, Health Services Manual, does not "mandate kidney transplantation." Rather, it states: "The Bureau will consider organ transplantation as a treatment option for inmates..." (emphasis mine.)

4. Upon revision of BOP policy regarding organ transplantation, the seven Federal Medical Centers (FMCs) were directed to solicit contract services for organ transplantation from community hospitals within a 200 mile radius of the FMC. Solicitations were to include requests for the following types of organ transplants: kidney, liver, heart, and heart-lung. To date, we have only secured contracts for bone marrow transplants (one site), and living-related kidney transplants (two sites). These are major university

medical centers. All transplant centers contacted to date have expressed no interest in entering into a contract which would result in the placement of Federal inmates on waiting lists for cadaver organs. Although this could be attributed to bias or value judgements related to inmates, there are a number of legitimate practical considerations, primarily related to the current regional structure of the Organ Procurement Organizations. A full description of these issues is outside the scope of this declaration.

5. There is no "community standard" with regard to kidney transplantation or the transplantation of other organs. Organ transplantation as the treatment of last resort for various conditions continues to be an evolving art and science. When deciding whether a given individual would benefit more from a kidney transplant than from continued dialysis, many factors must be considered. These factors include the age and general health of the patient, the effectiveness of current dialysis, the adequacy of vascular access for the dialysis procedure, and the presence of other chronic diseases or infections which may affect the long-term survival of a transplanted kidney.

6. There are two additional specific assertions made by

Mr. Barron which I am able to address as a matter of policy. First, Mr. Barron states on page 8 that "...the defendants failed to act with the required organ sharing kidney donor list to exchange the kidney provided by the plaintiff's family members to gain the matched kidney for the plaintiff." There are a number of problems with this statement. First, there is no requirement for any transplant center to participate in an organ sharing arrangement, whereby an individual with willing but unmatched donors is given a matched, cadaver kidney in exchange for a kidney from a living donor. This is a relatively new concept, in an attempt to increase the supply of kidneys. This is ethically problematic in that there are risks to the living donor. The second problem with Mr. Barron's statement is the implication that the BOP can place an inmate on a waiting list for a cadaver organ. Only institutions which are accredited by the United Network for Organ Sharing (UNOS), and which perform organ transplants, may add or remove a patient from a waiting list. The second specific assertion I will refute is found on page 21: "The defendants delayed and denied the plaintiff's kidney transplantation protocol based on budget constraints." When BOP policy was changed in February, 2000, we recognized that the cost implications were significant. A

specific cost center was established to cover not only the cost of a transplant surgery, but also the array of medical evaluations required in order to determine if an inmate is an appropriate candidate to undergo transplantation. No specific ceiling was established for this cost center; all appropriate costs are applied against the BOP's overall health care budget. That being said, the man-hours required to evaluate of over 200 inmates on dialysis for transplant consideration needs to be balanced against the delivery of medically necessary health care to a population of 4000 inmates being treated at any one time at all of the FMCs.

7. Throughout Mr. Barron's complaint runs the allegation that the BOP has not acted in a timely manner with regard to his evaluation for a possible kidney transplant. Globally, when considering how to prioritize these evaluations in the context of the management of many other inmates with significant medical needs, the logical approach is to identify those inmates on dialysis who are the most ill, but still healthy enough to tolerate the surgery and the rigorous post-transplant lifestyle. For dialysis patients, the highest priority should be given to those who have extremely limited vascular access

through which to continue dialysis, and those whose condition is consistently deteriorating despite dialysis. To my knowledge Mr. Barron does not meet either of these two criteria, yet over the past three years has undergone a stepwise evaluation toward the possibility of transplantation. The inmates who have been reviewed at the Central Office level for transplant consideration, on the other hand, do meet one or both of those acuity criteria.

I declare under penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct.

Executed this 24TH day of May, 2004, in Washington, D.C.

Michael B. Nelson, D.O.
Chief of Health Programs